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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,517	01/03/2002	Xuanchuan Sean Yu	LEX-0293-USA	6008

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EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,517	YU ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The application has been amended as requested in the communication filed August 2, 2004. Accordingly claim 2 has been cancelled, claim 1 has been amended, and new claims 5-8 have been entered.

Claims 1, and 3-8 are pending and under consideration.

The abstract of the disclosure is objected to because it does not describe the claimed invention. Correction is required. See MPEP ' 608.01(b).

Applicant has failed to response to this objection.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, and 3-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility

Claims 1, and 3-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above and set forth in the prior Office action mailed February 6, 2004.

In response to the above rejections, the examiner discounts many of the numerous utilities described in the specification for the lipase encoding sequence of the present invention.

Applicants arguments filed August 2, 2004 have been fully considered, but they are found unpersuasive. Applicant cite *In re Brena* to support their argument that PTO stepped out of the legal boundaries in making the utility rejection, but the issues regarding *In re Brena* was never raised by the examiner because there was no claims directed to a pharmaceutical composition and their use. In fact, the specification does not associate the polypeptide with any specific disease or biological function. Such

association would have been sufficient to overcome the utility rejection. With regard to U. S. patent 6,558,936 ('936), it is an issued patent having a different disclosure from the instant application, and presumed valid, and it is not currently under examination. Applicant should note that, in order to comply with the utility requirement under 35 U. S. C. 101, the application must contain a specific or substantial utility at the time the application was filed. As indicated in the previous Office action, applicant has asserted that the polypeptide of SEQ ID NO: 2 is a lipase, but he has failed to identify a specific or substantial utility for the claimed nucleic acid or the polypeptide encoding thereby. As indicated by the applicant, the lipase of '936 is different from that of SEQ ID NO: 2, and therefore, may have different utility or biological function. Also, applicant points out to a protein in a database having 99% sequence homology to SEQ ID NO: 2 and is describe as lipase. The examiner agrees with the applicant that the polypeptide of SEQ ID NO: 2 is more likely than not to be a lipase, but the application does not provide SEQ ID NO: 2 of the instant application with a specific or substantial utility at the time the application was filed. Contrary to the ligase of example 10 in the PTO utility guidelines wherein any two pieces of DNA are the substrate for said ligase, lipases as a group of enzyme have many substrates having diverse chemical structure and function, and are involved in many biological processes. Finally, the use of the nucleic acid sequence of SEQ ID NO: 2 in forensic analysis, DNA chips, and gene mapping do not support a specific or substantial utility for nucleic acid sequence of the instant application. New claims 5-8 are included in this rejection because they are drawn to vector and a host cell comprising the nucleic acid of claims 1, 3, and 4. Since the nucleic acid of claims 1, 3, and 4 lack utility, the vector and host cell comprising the nucleic acid also lack utility.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1 and 3-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Guegler *et al.* (US 2002/0052034 A1) for the reasons set forth above and set forth in the prior Office action mailed February 6, 2004.

In response to this rejection, applicant argues that they have no way to assess this rejection because they have no access to the priority document U. S. Provisional application 60/235,925, filed September 28, 2000.

Applicants arguments filed August 2, 2004 have been fully considered, but they are found unpersuasive. First, this rejection is not a provisional rejection until the issuance of a U. S. patent based on the published document; see the statutory bases for this rejection cited above. The rejection is based on the published document itself and the cited priority in it. Second, a copy of the provisional application is available to applicant upon request, and it is currently available on line, see below. The MPEP, section 103 on pages 100-107 of the August 2001 revision, recognizes the need of an applicant to obtain copies of priority documents and provides a mean of obtaining the appropriate priority document as it states:

> "The incorporation by reference of a pending application in a U.S. patent application publication, a U.S. patent, or a published international application designating the United States constitutes a special circumstance under 35 U.S.C. 122 warranting that a copy of the application-as-filed be provided upon written request. In addition, if a U.S. patent application publication, a U.S. patent, or a published international application designating the U.S. claims benefit under 35 U.S.C. 119(e) or 120 to a U.S. patent application, a copy of that application-as-filed may be provided upon written request. **The written request, including a copy of the page of the patent application publication, U.S. patent, or published international application including the incorporation by reference or specific reference under 35 U.S.C. 119(e) or 120, and the requisite fee set forth in 37 CFR 1.19(b)(1), should be directed to the Certification Division.** However, an incorporation by reference that is made as part of a transmittal letter for the application, or that is a part of the text of the application that has been canceled and which does not appear as part of the printed patent, may not be relied upon to obtain a copy of the application as originally filed. A petition for access with an explanation of special circumstances other than the not-printed incorporation by reference will be required."

Recently, a provisional application which is cited as priority document for a published application or patent are available on the internet through the Patent Application Information Retrieval (PAIR) since October 2004.

New claims 5-8 are included in this rejection because they are directed to a vector and host cell comprising the claimed nucleic acid, which is taught by Guegler *et al.*, see starting with paragraph 163 through paragraph 190.

No claim is allowed.

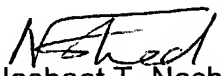
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652